

REMARKS

Status of Claims and Amendment

Upon entry of the amendment, which is respectfully requested, claims 4, 10 and 16-18 will be amended. Claims 8 and 10 are withdrawn from consideration. Claims 4, 6 and 16-18 are rejected.

Claims 4, 17 and 18 have been amended to recite "a biologically pure culture of" and to recite the complete taxonomical name of the claimed species, *i.e.*, "*Lactobacillus plantarum*." Support for these amendments can be found at least at page 9, lines 7-10, and page 12, lines 10-12, of the present specification.

Claim 16 has been amended to recite "effervescent product" instead of "effervescent tablet." Support for the amendment to claim 16 can be found at least at page 23, lines 10-12 of the present specification.

Claim 10 has been amended to correct a self-evident grammatical error.

Support for the amendment to the specification can be found in Francoise BRINGEL et al., "Lactobacillus plantarum subsp. argenteratensis subsp. nov., isolated from vegetable matrices", International Journal of Systematic and Evolutionary Microbiology, 2005, 55: 1629-1634 enclosed herewith.

No new matter is added.

Claim to Priority

Applicants respectfully request that the Examiner acknowledge Applicants' claim to foreign priority, and acknowledge receipt of a certified copy of Applicants' foreign priority document, namely Japanese Application No. 2004/012136.

Information Disclosure Statements

Applicants thank the Examiner for returning copies of the PTO Forms SB/08 that accompanied the Information Disclosure Statements filed February 17, 2006, May 17, 2006, and May 2, 2007. However, the Examiner indicates that copies of *Perdigon et al.* (2001), *Perdigon et al.* (1999) and *Maasen et al.*, cited in the Information Disclosure Statement filed May 2, 2007, were not provided, and thus have not been considered.

Initially, Applicants note that the *Perdigon et al.* (1999) reference was cited by the Examiner in the outstanding Office Action, and the *Perdigon et al.* (2001) reference was cited by the Examiner in the Restriction Requirement mailed April 28, 2008, obviating the need to submit these references in an Information Disclosure Statement.

Nevertheless, Applicants provide herewith a copy of the *Maasen et al.* reference in the concurrently-filed Information Disclosure Statement.

Response to the Claim Objections

At page 2 of the Office Action, the Examiner indicates that the bacterial species' names recited in claims 4, 17 and 18 are not capitalized in accordance with domestic and scientific practice. For clarity, claims 4, 17 and 18 are amended herewith to recite that the claimed strains are of the species "*Lactobacillus plantarium*."

Applicants respectfully submit that the amendments overcome the rejection.

Withdrawal of the rejection is respectfully requested.

Response to Rejections Under 35 U.S.C. §101

At page 2 of the Office Action, claims 4, 6 and 16-18 are rejected under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter. Specifically, the Examiner contends that such claims encompass organisms found in nature. The Examiner suggests that amending the relevant claims to recite “biologically pure culture” may obviate the rejection.

Solely to advance prosecution, and without acquiescing to the merits of the rejection, claims 4, 17 and 18 are amended herewith to recite that the claimed composition comprises “a strain of lactic acid bacteria selected from the group consisting of a biologically pure culture of *Lactobacillus plantarum* ONRIC b0239 (FERM BP-10064) and a biologically pure culture of *Lactobacillus plantarum* ONRIC b0240 (FERM BP-10065).”

Applicants respectfully submit that the amendments overcome the rejection.

Withdrawal of the rejection is respectfully requested.

Response to Rejections Under 35 U.S.C. §112

1. Indefiniteness

At page 3 of the Office Action, claims 4, 6 and 16-18 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

In one aspect of the rejection, the Examiner asserts that the specification recites that the strains belong to “*Lactobacillus plantarum*,” but that the claims simply recite “*Lactobacillus*.” The Examiner alleges that such renders the claims indefinite.

In a second aspect of the rejection, the Examiner asserts that claim 16 is confusing inasmuch as the composition forms recited in claim 16 are not consistent with those recited in claim 4. Specifically, the Examiner contends that claim 16 fails to find proper antecedent basis

in claim 4 for “granules, a powder, a tablet, an effervescent tablet” and alleges that these materials do not constitute proper “foodstuffs or beverages.”

Regarding the first aspect of the rejection, in the interest of compacting prosecution, Applicants herewith amend claims 4, 17 and 18 to recite “*Lactobacillus plantarum*,” overcoming the rejection.

Regarding the second aspect of the rejection, namely that claim 16 fails to find proper antecedent basis in claim 4, Applicants respectfully disagree.

Initially, Applicants respectfully point out that page 16, line 20 to page 17, line 1 of the present specification clearly discloses granules, powders, tablets and effervescent tablets, as exemplary food stuffs or beverages of the present invention. As such, claim 16 properly depends from claim 4.

Reconsideration and withdrawal of the rejection under § 112, second paragraph, is respectfully requested.

2. Enablement

At page 3 of the Office Action, claims 4, 6 and 16-18 are rejected under 35 U.S.C. §112, first paragraph, as lacking enablement.

The Examiner asserts that, to comply with the enablement requirement of §112, first paragraph, a suitable deposit of the instantly claimed strains is required accompanied by a Statement of Availability pertaining thereto.

Initially, Applicants note that on pages 9 and 12 of the specification as filed, it is disclosed that the instantly claimed strains were deposited at the “National Institute of Advanced Industrial Science and Technology International Patent Organism Depositary, AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken, Japan on August 6, 2003.”

Applicants attach herewith a Statement of Availability pertaining thereto, overcoming the rejection.

Reconsideration and withdrawal of the rejection under § 112, first paragraph, is respectfully requested.

Response to Rejections Under 35 U.S.C. § 102(b) and § 103(a)

At page 4 of the Office Action, claims 4, 6 and 16-18 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by or, in the alternative, obvious under 35 U.S.C. § 103(a) over Ikenaga *et al.* (Milk Science, 2002, 51: 27-32), Perdigon *et al.* (J. Dairy Sci., 1999, 82: 1108-1114) or Herias *et al.* (Clin. Exp. Immunol., 1999, 116: 283-290).

The Examiner asserts that the claims are directed to *Lactobacillus* strains capable of stimulating mucosal immunity. The Examiner alleges that the cited references each disclose a *Lactobacillus plantarum* strain which appears to be identical to the presently claimed strain, because such strains allegedly stimulate mucosal immunity.

Further, the Examiner alleges that, even if the claimed microorganism is not identical to the referenced microorganism, the referenced microorganism would inherently possess the same characteristics as the claimed microorganism, rendering obvious the presently claimed invention.

Applicants respectfully disagree, and traverse on the following grounds. First, Applicants respectfully point out that claims 4, 17 and 18 recite a pharmaceutical composition comprising a *Lactobacillus plantarum* strain and an edible carrier (*i.e.*, claim 4) or a pharmacologically acceptable carrier (*i.e.*, claims 17 and 18). Relevant law holds that “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. (See *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Ikenaga *et al.*, Perdigon *et al.* or

Herias *et al.* do not disclose, either expressly or inherently, an edible carrier or a pharmaceutically acceptable carrier. Accordingly, the cited references do not anticipate Applicants' presently claimed invention for this reason alone.

Regarding the Examiner's contention that the claimed strains, if not anticipated by the cited references are rendered obvious, Applicants respectfully disagree. First, Applicants provide comparative data, in Rule 132 Declaration form, demonstrating that the instantly claimed strains possess an unexpectedly superior property of promoting IgA production and stimulating mucosal immunity. Specifically, a comparison vis-à-vis *Lactobacillus plantarum* ONC141 (disclosed in Ikenaga), and *Lactobacillus plantarum* 299V (disclosed in Harias), is set forth in the Declaration. As depicted in Table II, only *Lactobacillus plantarum* strains ONRIC b0239 (FERM BP-10064) and ONRIC b0240 (FERM BP-10065), as claimed, stimulate IgA production to an S.I. value of 5 or more. On the other hand, the IgA S.I. value of *Lactobacillus plantarum* 299v (disclosed in Harias) is 2.16.

Further, as shown in the attached Declaration, the total IgA content of human saliva (saliva SIgA) produced by administration of *Lactobacillus plantarum* ONC141 (disclosed in Ikenaga), or the instantly claimed *Lactobacillus plantarum* ONRIC b240, was compared. While there was no increase in IgA content when *Lactobacillus plantarum* ONC 141 was administered, *Lactobacillus plantarum* ONRIC b240 administration induced a significant increase in IgA in the saliva.

Further still, as shown in Example 2 of the present application, and in the attached Declaration, all of the tested *Lactobacillus plantarum* strains other than the claimed strains ONRIC b0239 and ONRIC b0240 exhibited less than half of the IgA S.I. values. Accordingly, the instantly claimed strains possess unexpectedly superior IgA-stimulating activity vis-à-vis the

strains of the cited references, and such is probative of the non-obviousness of the claimed invention. It is well-settled that a demonstration of unexpected results, or unexpected superiority of a particular result or property, may rebut a finding of obviousness. Applicants respectfully submit that in view of such unexpectedly superior properties of the instantly claimed invention, the cited references, taken above or in combination, do not render obvious Applicants' claimed invention.

Reconsideration and withdrawal of the rejection under § 102(b) and § 103(a) is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Susan J. Mack/

Susan J. Mack
Registration No. 30,951

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: March 13, 2009